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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,061	05/19/2000	STEPHAN R. TARGAN	P-PM 4097	1578

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/03/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/575,061	TARGAN ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *8-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 5/9/03 in Paper No. 22 is acknowledged and has been entered. Claim 3 has been amended. Claims 1-11 are pending. Claims 1-7 are under examination.

Election/Restrictions

2. Applicant argues that the search of elected claims 1-7 would be coextensive with the search of claims 8-11 because both groups involve determining the presence of anti-OmpC antibodies in a sample from a subject suspected of having inflammatory bowel disease. According to Applicant, a search of the methods of claims 1-7 will encompass literature that describes testing only for IgA anti-OmpC antibodies or testing for IgA anti-OmpC antibodies with other substances; therefore, literature relevant to claims 8-11 which involves determining other diagnostic markers would be identified by a search for claims 1-7. Applicant also argues that a review of [additional] references relevant to the limitations recited in claims 8-11 would not impose a serious burden on the Examiner; thus rendering the restriction requirement improper.

In response, while searches would be expected to overlap as suggested by Applicant, there is no reason to expect the searches to be coextensive because the claims recite specific, separate, and distinct additional diagnostic markers which thus, render the claims independent from the other for having different structural

requirements for each invention. Contrary to Applicant's contention, a search of keyword "A", even if it existed in relation to keywords "B", "C", "D", may result to relevant literature including keywords "B", "C", and "D", but not necessarily so, unless a keyword search for each of "B", "C", and "D" is also executed and reviewed for relevancy, novelty, and obviousness in relation to the limitations identified by the claimed invention. Therefore, Applicant's argument that examination of all the claims would not pose undue burden to the examiner is without merit.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for all of IgA outer membrane protein C (OmpC) antibody, anti-Saccharomyces antibody (ASCA), I-2 polypeptide antibody (I-2 antibody), and perinuclear anti-neutrophil antibodies (pANCA) as cumulative diagnostic markers or diagnostic system for use in a method for diagnosing the presence of Crohn's disease, does not reasonably provide enablement for using only solely IgA anti-OmpC antibody as a diagnostic marker for diagnosing the presence of Crohn's disease. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is being maintained for reasons of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 2-7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite because it implies but does not definitely or specifically recite, that the IgA OmpC antibodies bind to the reactive epitope of OmpC antigen or its reactive fragment.

Claim 3 is vague and indefinite because it implies but does not definitely or specifically recite, that the IgA OmpC antibodies bind to the reactive epitope of OmpC antigen having SEQ ID NO. 1 or its reactive fragment.

The term "substantially" in claim 3 is a relative term which renders the claim indefinite. The term "substantially" in the context of amino acid sequence is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Response to Arguments

5. Applicant's arguments filed 5/9/03 have been fully considered but they are not persuasive.

A) Applicant contends that the specification is enabled for a method of diagnosing Crohn's disease by determining the presence of IgA anti-OmpC antibodies alone as a diagnostic marker because a diagnostic method need not be 100% sensitive to be useful and valuable and that many diagnositic tests fall well below 100% sensitivity (as submitted in Bulletin 1).

Applicant's argument is not on point. The rejection of claims 1-7 are based on a lack, i.e.scope, of enablement of Applicant's disclosure. To reiterate, claims 1-7 are enabled for using a cumulative combination of markers including IgA anti-OmpC antibody, ASCA, I-2 antibody, and pANCA as a diagnostic system in diagnosing the presence of Crohn's disease but are not reasonably enabled for using only solely IgA anti-OmpC antibody as a diagnostic marker for diagnosing the presence of Crohn's disease. Specifically, the specification only provides that the presence of IgA anti-OmpC antibody is contributory to the diagnosis of Crohn's disease. Throughout the specification, the combination of diagnostic markers consisting of IgA anti-OmpC antibody, ASCA, I-2 antibody, and pANCA are used to provide a diagnosis of Crohn's disease. The specification fails to show IgA anti-OmpC antibody as being the sole diagnostic marker in diagnosing Crohn's disease as recited in the claims. All embodiments set forth in pages 4-5 of the specification use IgA anti-OmpC antibody in combination with one or more of ASCA, I-2 antibody, and pANCA as a diagnostic

system in diagnosing the presence of Crohn's disease. Page 6 specifically indicated that IgA OmpC antibody reactivity together with ASCA reactivity, I-2 antibody reactivity, and pANCA reactivity provides a highly sensitive diagnostic system. Further, none of the working examples suggest or support Applicant's claim of using only IgA anti-OmpC antibody as a sole diagnostic marker for Crohn's disease. Accordingly, the rejection under 35 U.S.C. 112, first paragraph, is being maintained.

6. For reasons aforementioned, no claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

Gailene R. Gabel
Patent Examiner
Art Unit 1641
September 22, 2003